Edwards Lifesciences
One Edwards Way • Irvine, CA USA • 92614
Phone: 949-250-2500 • Fax: 949-250-2525
www.edwards.com

K091707

5 510(k) Summary

Submitter:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614-5686
Contact Person:	Jason Smith Regulatory Affairs Manager
Date Prepared:	June 9, 2009
Trade name:	Multi-Med Central Venous Catheters
Classification Name:	Catheter, Intravascular, Therapeutic, Short-Term, less than 30 days (21 CFR 880.5200)
Predicate Devices:	1. Multi-Med CVC; cleared under K955839 (March 25, 1996) 2. ArrowG+Ard, Arrow G+ Blue Plus Pressure Injectable CVC; cleared under K071538 (August 30, 2007)
Device Description:	The Multi-Med CVCs are single use devices available in 7 or 8.5 French outside diameter, 2-4 lumens, 16 or 20 cm length. The catheters may be coated with AMC Thromboshield benzalkonium chloride heparin coating.
Intended Use:	The Multi-Med CVCs are intended to provide access to the central venous system, infusion of solutions, blood sampling, and central venous pressure monitoring.
Comparative Analysis:	The Multi-Med CVCs have been demonstrated to be as safe and effective as the predicate devices for their intended use.
Functional/Safety Testing:	The Multi-Med CVCs have successfully undergone functional testing. These products have been shown to be equivalent to the predicate devices.
Conclusion:	The proposed Multi-Med CVCs are substantially equivalent to the predicate devices.

OCT 13 2009

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 16 2009

Mr. Jason Smith
Manager of Regulatory Affairs
Edwards Lifesciences, L.L.C.
One Edwards Way
Irvine, California 92614-5686

Re: K091709
Trade/Device Name: Multi-Med CVCs and Vantex CVCs
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: September 30, 2009
Received: October 2, 2009

Dear Mr. Smith:

This letter corrects our substantially equivalent letter of October 13, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091709
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Indications for Use Statement

510(k) Number (if known): K091709

Device Name: Multi-Med CVCs

Indications for Use:

The Multi-Med catheter is indicated for use in patients requiring administration of solutions, blood sampling, central venous pressure monitoring, and injection of contrast media.

Device Name: Vantex CVCs

Vantex central venous catheters are indicated for use in patients requiring administration of solutions, blood sampling, central venous pressure monitoring, and injection of contrast media. All catheters include a soft tip to reduce the risk of vessel perforation.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091709